

USDA's Biotechnology Notification Process

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), through its Biotechnology Regulatory Services (BRS) program, is responsible for regulating the introduction (importation, interstate movement, and field release) of genetically engineered (GE) organisms such as plants, insects, microorganisms, and any other organism that is known to, or could be, a plant pest. Through a strong regulatory framework, BRS ensures the safe and contained introduction of new GE plants with significant safeguards to prevent the accidental release of any GE material. BRS is committed to the continual development of a regulatory framework that reflects the latest science and research, while continuing to protect America's agriculture.

BRS regulates the introduction of GE organisms through two processes: permitting and notification. Notification is an expedited permitting process for those GE organisms that BRS considers to be lower risk and has extensive experience regulating in the past. The GE material may alter the agronomic properties of the plant, such as changing the yield, drought or cold tolerance, pest resistance, or nutritional components.

To qualify for the notification process, the GE plant must meet six eligibility requirements relating to the weed status of the plant and the introduced genetic material, and it must be introduced in accordance with BRS' specified performance standards to ensure confinement of the GE material.

BRS requires detailed information about the plant, such as the source and identity of any genes introduced; the method of genetic engineering; and the size, duration, and location of the field test. BRS must receive notification from any entity wishing to introduce a GE plant at least 10 days before the interstate movement of the organism and no less than 30 days before field testing or importation of the plant. This timeframe is necessary to allow BRS employees time to review the notification and ensure that the product does qualify for the expedited processing. Detailed followup reports are also required for field testing under notification, just as they are under the permitting process.

In 1997, the notification process was expanded from the six crop species originally eligible in 1993 to include introductions of all GE plants that meet BRS eligibility criteria and performance standards. Introductions of GE plants engineered to express pharmaceuticals or new industrial compounds for non-food/feed uses are not eligible for notification. If a plant does not meet notification eligibility criteria, the permit process must be followed for movement, importation, or field testing.

Eligibility Requirements for Notification

Any GE organism introduced under the notification process must meet all six eligibility criteria. BRS designed these criteria to ensure that the GE material being introduced is low risk. The criteria are as follows:

- The plant must not be listed on the Federal Noxious Weed list or be considered a weed in the area of proposed release.
- The introduced genetic material must be stably integrated, which means the introduced DNA must remain inside the cell and replicate exclusively by mechanisms used by the recipient organism.
- The function of the introduced genetic material is known, and its presence in the regulated article does not result in a plant disease.
- The introduced genetic material does not cause the production of an infectious entity, produce substances that are known to be, or are likely to be, toxic to nontarget organisms, or produce products intended for pharmaceutical or industrial use.
- The introduced genetic sequences derived from plant viruses do not pose a significant risk to the creation of any new plant virus. For information on eligible plant virus-derived sequences, please contact BRS.
- The plant has not been modified to contain certain genetic material derived from an animal or human pathogen. In addition, plants containing coding sequences whose products are known agents of diseases in humans or nontarget animals are not eligible.

Performance Standards for Notification

BRS requires companies or institutions utilizing the notification process to adhere to six performance standards that ensure complete confinement of the GE material. The goal of these standards is to manage the regulated article so that neither it nor its offspring is released into, or persists in, the environment.

The six performance standards are as follows:

- The introduced regulated article must be shipped to and maintained at the destination facility in a manner so that there is no release into the environment. There must be no inadvertent mixing of regulated articles and nonregulated articles.
- The regulated plant material should be maintained in such a way that the identity of all material is known. When the tests are complete, the plant material must be contained or killed.
- When the transformation process uses a live microorganism as a vector to introduce the genetic construct, the transformed plant should be free of the microorganism at the time of introduction.
- The regulated article or its offspring cannot persist in the environment.
- No viable plant material (e.g. seeds or propagules) shall remain that is likely to volunteer, or volunteers must be monitored and managed to prevent persistence in the environment.

Additional Information

For more information about the notification process for the introduction of genetically engineered organisms, contact:

USDA, APHIS, BRS
4700 River Road, Unit 147
Riverdale, MD 20737
Telephone (301) 734-7324 or visit the APHIS
Web site at <http://www.aphis.usda.gov>.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 1400 Independence Avenue, SW, Washington, DC 20250-9410 or call (202) 720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.